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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,733	05/20/2005	Osamu Ohara	1254-0282PUS1	2831
2292 7590 12/09/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER GUSLOW, ANNE				
ART UNIT 1643		PAPER NUMBER		
NOTIFICATION DATE 12/09/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/535,733

**Applicant(s)**

OHARA ET AL.

**Examiner**

ANNE M. GUSSOW

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4, 5 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 18 and 19 have been amended.

No claims have been canceled or added.

Claim 20 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 17, 2006.

2. Claims 1, 2, 4, 5, 18, 19, and 21 are under examination.
3. The following Office Action contains NEW GROUNDS of Rejection.

***Objections Maintained***

4. The objection to claims 4, 5, 19, and 21 is maintained.

Applicant's response filed August 8, 2008 has been carefully considered but is deemed not to be persuasive. The response states that the Examiner objects to claims 4, 5, 19 and 21. However, the Examiner provides no reasoning or support for the objection (see response page 8).

In response to this argument, these claims depend from a rejected base claim, claim 2. If claims 4, 5, and 21 were written to depend solely on claim 1, instead of claims 1 or 2, they would appear to be in condition for allowance.

Therefore after a fresh consideration of the claims and the evidence provided the objection is maintained.

***Rejections Maintained/NEW GROUNDS of Rejection***

***Claim Objections***

5. Claim 18 is objected to because of the following informalities: the claim recites a DNA molecule with an amino acid sequence. For example, "the following DNA (a)-(f): (a) a polypeptide, consisting of an amino acid sequence". For purposes of this office action the claim is being read as "the DNA encoding the polypeptide of SEQ ID No. 2" in parts (a) and (b). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. The rejection of claims 2 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite is maintained.

Applicant's response filed August 8, 2008 has been carefully considered but is deemed not to be persuasive. The response states that although Applicants do not agree that the claims are indefinite, the claims have been amended to be directed to the peptides of SEQ ID NOS: 3 and 4, in addition to the stringent hybridization conditions already recited in the claims. The claimed DNA of claim 2 and claimed polynucleotide of claim 18 are restricted to those which hybridize under stringent conditions, i.e. 1 X

SSC, 0.1% SDS, and 37 °C. In the hybridization process, a washing step is carried out to remove DNAs which should not hybridize and cause background signal. That is, "DNA hybridize under stringent condition, 1 X SSC, 0.1% SDS, and 37°C" means DNA which can hybridize under the said condition and maintain hybridizing when washed under the same condition (see response pages 5-6).

In response to this argument, one of ordinary skill in the art would know that the stringency of hybridization is affected by the stringency of the washes. Typically the salt concentration of the wash solution determines the amount of probe which remains bound to the target during the washing steps.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The rejection of claim 18 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is maintained.

Applicant's response filed August 8, 2008 has been carefully considered but is deemed not to be persuasive. The response states that the claimed polypeptide of claim 18 possesses a feature that is a DNA encoding a region of amino acid sequence of SEQ ID NO: 2, the region having low sequence homology with other similar sequences. Accordingly, a person skilled in the art can clearly recognize that the

claimed polypeptide of claim 18 can be used as a probe to detect the DNA of claim 1. Amended claim 19 claims a polynucleotide consisting of a nucleotide sequence which is complementary to the nucleotide sequence encoding the amino acid sequence represented by SEQ ID NO: 3 or 4. It is clear that the polynucleotide can be used as a probe to detect the DNA of claim 1 (see response pages 6-8).

In response to this argument, the claim is drawn to a polynucleotide, not a polypeptide and the claimed polynucleotide is any polynucleotide which hybridizes under stringent conditions to any portion of the polynucleotide. The specification teaches the polynucleotide that encodes SEQ ID Nos. 3 and 4 and hybridizes to SEQ ID No. 2.

Regarding applicant's comments on claim 18 not being a genus claim, applicant is again confusing polypeptides and polynucleotides. The response states that "The claimed polypeptide of claim 18..." (see response page 8). Claim 18 is drawn to a polynucleotide which hybridizes to the molecules of any of (a) through (f), each of which would have more than a single hybridizing species thus the claim is broadly drawn to a large number of hybridizing polynucleotides. Further, the instant genus would contain a fair amount of variability because molecules which hybridize do not specifically bind to each and every residue of a sequence, therefore the structure of the hybridizing molecule would have significant variation.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

10. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed August 8, 2008 has introduced NEW MATTER into the claims. Newly amended claims 18 and 19 recite "the nucleotide sequence which is complementary to the nucleotide sequence encoding the amino acid sequence of SEQ ID No. 3 or 4 (see claim 18(f) and 19). The response did not point out where support for the amendments could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claims 18 and 19 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in claims 18 and 19, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 18 and 19 in the

specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

### ***Conclusions***

11. Claim 1 appears to be in condition for allowance.

Claims 2, 18, and 19 are rejected.

Claims 4, 5, and 21 are objected to.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 3, 2008

/David J Blanchard/  
Primary Examiner, Art Unit 1643